In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-551V

(not to be published)

A.S., *by his father and natural guardian,* GUY STERLING,	*	Special Master Corcoran
Petitioner,	*	Filed: August 27, 2019
v.	*	Autism Spectrum Disorder; Dismissal; Encephalopathy.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Clifford J. Shoemaker, Shoemaker, Gentry & Knickelbein, Vienna, VA, for Petitioner.

Voris E. Johnson, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION[1]

On May 5, 2016, Guy Sterling filed a petition on behalf of his minor son, A.S., seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] ECF No. 1. He initially alleged that "multiple vaccines" A.S. received on May 7, 2013, and July 26, 2013, caused or significantly aggravated unspecified injuries. *Id.* at 1. He later amended his claim to specify that the pneumococcal conjugate PCV-13, Hemophilus influenzae type B ("Hib") (PRP-T), and diphtheria-tetanus-acellular pertussis ("DTaP") vaccines

[1] Although I am not formally designating this Decision for publication, it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

administered to A.S. on May 7, 2013, caused neurologic neglect syndrome, expressive language disorder, unspecified disorders of the nervous system, and immune dysfunction. Am. Pet. at 3, filed Apr. 14, 2017 (ECF No. 24).

Asserting that A.S.'s proper diagnosis is autism, Respondent moved to dismiss Petitioner's claim with the filing of his Rule 4(c) Report on June 2, 2017. *See generally* ECF No. 27. Because the parties disputed A.S.'s diagnosis, both parties filed expert reports in support of their positions. After reviewing these reports, I decided to resolve this matter without hearing, and the parties filed briefs in support of their respective positions in the spring of 2019. *See* Mem. in Supp. of Entitlement, filed Mar. 29, 2019 (ECF No. 63) ("Mem."); Resp't's Resp. to Pet'r's Mem. in Supp. of Entitlement, filed May 9, 2019 (ECF No. 65) ("Opp."); Reply to Resp't's Resp. to Mem. in Supp. of Entitlement, filed May 28, 2019 (ECF No. 66) ("Reply").

Having now had the opportunity to review the medical records, expert reports, and arguments of both parties, I find that Respondent's motion to dismiss is well-founded. For the reasons set forth below, I hereby dismiss Petitioner's claim.

I. A.S.'s Medical History

Early History and May 2013 Vaccinations

A.S. was born at term via cesarean section on January 7, 2012. Ex. 1 at 4–5, filed July 22, 2016 (ECF No. 8-2). He was born healthy with no complications, and was discharged home on January 10th. *Id.* at 2. He received the Hepatitis B ("Hep B") vaccine on the day of his birth, with no recorded reaction. Ex. 2 at 79, filed July 22, 2016 (ECF No. 8-3). No concerns were noted at a newborn checkup with Stephen Cooper, M.D., on January 12th. *Id.* at 79–81.

Throughout the first nine months of his life, A.S. saw Dr. Cooper regularly for well-child visits. Ex. 2 at 64–78. A.S. presented with conjunctivitis at a January 20, 2012 visit, but this quickly improved with medication. *Id.* at 74, 77. A.S. next received the DTaP, Hib, polio, pneumococcal, and rotavirus vaccines, as well as a second round of Hep B, at a March 9th checkup. *Id.* at 73. He received a second round of DTaP, Hib, polio, pneumococcal, and rotavirus vaccines two months later on May 9th. *Id.* at 67. Dr. Cooper also recorded that A.S. had torticollis—a left head tilt—at the May 9th checkup. *Id.* at 69, 71. A.S. received a third round of the DTaP, Hib, polio, Hep B, pneumococcal, and rotavirus vaccines on July 12th, again without incident. *Id.* at 64–65. On September 20th, his mother brought him to see Jerry Clayville, M.D., concerned about an "occasional raspy sound" A.S. was making. *Id.* at 64. Dr. Clayville diagnosed A.Z. with gastroesophageal reflux and prescribed Zantac. *Id.* at 66.

At his nine-month well-child checkup on October 12, 2012, A.S.'s fine motor skills were characterized as "borderline," but no other concerns were noted. Ex. 2 at 60–63. He received the influenza ("flu") vaccine at this visit. *Id.* at 63. He received a second flu shot one month later on

November 13th. *Id.* at 56. At his twelve-month checkup on January 9, 2013, A.S. was able to stand independently, crawl, and say a few words. *Id.* at 54. He had eczema, but was otherwise normal on examination. *Id.* at 55. He received the measles-mumps-rubella ("MMR"), varicella, and Hepatitis A ("Hep A") vaccines on this date. *Id.* at 55. Six days later on January 15th, A.S. presented to Dr. Clayville with cough, loss of appetite, and a fever, which Dr. Clayville thought might be a viral syndrome with croup-like features. *Id.* at 49–52. He also suspected that A.S. had viral-induced leukopenia and neutropenia. *Id.* at 52. A.S. was referred to the emergency room ("ER") for further evaluation, where he was diagnosed with a viral disease. Ex. 3 at 4, filed July 22, 2016 (ECF No. 8-4). A.S. returned to the ER just over one month later on February 24th with a fever, cough, ear pain, and a runny nose. *Id.* at 10–11. He was again diagnosed with a virus. *Id.* at 12.

On May 7, 2013, A.S. saw Dr. Clayville for his fifteen-month checkup. Ex. 2 at 40. No developmental concerns were noted, and A.S. was then able to say more than six words. *Id.* at 42. He received his fourth DTaP, pneumococcal, and Hib vaccinations at this visit. *Id.* at 43. The medical record shows no evidence of a reaction to these vaccinations, and when A.S. next saw Dr. Clayville for a checkup on July 26th, the Sterlings made no recorded mention of a post-vaccination reaction any time after the previous visit. *Id.* at 38. At the July 26th visit, A.S. passed a developmental screen,[3] and his vocabulary was documented as "7+ words." *Id.* at 38–39. He received a second Hep A vaccine, again with no documented reaction. *Id.* at 39. Three months later, on October 15th, A.S. saw Dr. Clayville for receipt of the flu vaccine. *Id.* at 32. No assessment of A.S.'s development was made at that visit, but neither were developmental concerns reported. *See id.* He was later seen on November 19th for cold symptoms without fever, which Dr. Clayville diagnosed as an upper respiratory infection. *Id.* at 26–29.

Recorded Reports of Developmental Delay

A.S.'s developmental delay was first noted at his two-year well-child visit on January 27, 2014 (now eight months after the May 2013 vaccinations). Ex. 2 at 21–26. At this time, Dr. Clayville observed that A.S. knew fewer than ten words, and that he "seem[ed] to be decelerating in acquisition of words." *Id.* at 24. He failed communication and problem solving components of a developmental screening, and was "borderline" in the personal-social skills category. *Id.* at 25. His condition was assessed as expressive language delay, and Dr. Clayville noted concern for a possible autism spectrum disorder ("ASD"). *Id.* at 26.

In the weeks following Dr. Clayville'sassessment, A.S. underwent evaluations by several specialists. He saw a speech therapist on February 3, 2014. Ex. 11 at 22–25, filed Nov. 29, 2016 (ECF No. 13-9). He was assessed with "a severe receptive and expressive language disorder," which the speech therapist thought could be attributed to hearing deficits, "or some other

[3] Although this developmental screening was performed as A.S.'s eighteen-month checkup, the age group listed for the screening is nine months. Ex. 2 at 39. There is no clear explanation in the medical record for this discrepancy.

underlying pathology which warrants assessment of hearing acuity and behavioral concerns." *Id.* at 24–25. A.S. next saw an ear, nose, throat, and allergy specialist, Michael Kelleher, M.D., on February 7th. Ex. 6 at 2–4, filed Nov. 29, 2016 (ECF No. 13-4). Dr. Kelleher found A.S.'s hearing to be normal, and diagnosed him with gastroesophageal reflux and "[o]ther developmental speech or language disorder." *Id.* at 2. The Sterlings reported to Dr. Kelleher that A.S. "may demonstrate some of the features of Autism." *Id.* at 3. Dr. Kelleher explained that he was not qualified to opine as to the accuracy of a possible ASD diagnosis, and that they should consult with a pediatrician or childhood development specialist. *Id.* Six days later, A.S. underwent a developmental evaluation, in which he was described as having a 25% delay in communication, cognitive, and social-emotional skills. Ex. 17 at 34–36, filed Nov. 29, 2016 (ECF No. 14-6).

A.S. saw an occupational therapist on July 16, 2014. Ex. 11 at 28–32. At this evaluation, the Sterlings reported that A.S. "had been doing very well with meeting his milestones until he got a viral infection after his immunization shots and he had a very high fever," after which "he seemed to [lose] some of his language skills and seemed to get further and further behind." *Id.* at 28. His diagnosis at this evaluation was "neurologic neglect syndrome." *Id.* At a physical therapy exam on October 7th, A.S.'s condition was characterized as "developmental delay" and "unspecified disorder of the nervous system." *Id.* at 35, 37. His feet were noted to rotate inward, and he exhibited gross motor delays. *Id.* at 35–36.

The Sterlings continued to seek out further evaluation and treatment options in 2015. In January of that year, they saw another ear, nose, and throat specialist, Matthew Kashima, M.D. Ex. 7 at 4–5, filed Nov. 29, 2016 (ECF No. 13-5). The Sterlings reported concerns about A.S. having ear pain, sound sensitivity, or deficits in his hearing and comprehension ability, as well as possible seasonal allergies. *Id.* at 4. They had tried various treatments, including a hyperbaric chamber and diet modifications. *Id.* Dr. Kashima prescribed nasal steroids. *Id.* at 5. Subsequently, the Sterlings took A.S. to see Howard Kader, M.D., for a gastroenterology evaluation on February 10, 2015. Ex. 5 at 4–9, filed Nov. 29, 2016 (ECF No. 13-3). Based on their report, Dr. Kader recorded that A.S. "stooled normally as an infant until after his MMR was given," after which he was "found to have leuko[p]enia and evaluated in the ER and felt related to his 1 year vaccination immune reaction." *Id.* at 5. A.S. was noted to have many problems related to digestion and bloating. *Id.* Dr. Kader discussed a wide range of possible diagnoses, including irritable bowel syndrome, celiac disease, and pancreatic insufficiency, and he recommended lab tests and a follow-up consultation. *Id.* at 8.

On March 23, 2015, A.S. saw Richard Layton, M.D. Ex. 14 at 38–42, filed Nov. 29, 2016 (ECF No. 14-3). Dr. Layton recorded five pages of handwritten notes from this initial visit, providing a detailed assessment of A.S.'s condition largely consistent with what other records reflect. *See id.* He described A.S.'s developmental delay and speech regression, stating that no formal evaluation had been made to date on these concerns. *Id.* at 39. A.S.'s gastrointestinal difficulties, food reactions, possible allergies, gait abnormalities, and more were all recorded in

Dr. Layton's notes. *Id.* at 38–42. Dr. Layton made no mention of encephalopathy or other brain injury in the detailed notes from this initial consultation. *See id.* However, a billing statement from this visit—which lists procedures and diagnoses along with their billing codes—contains a check mark next to "encephalopathy." Ex. 16 at 54–55, filed Nov. 29, 2016 (ECF No. 14-5).

The Sterlings prepared several documents in conjunction with their visits to Dr. Layton. A self-reported medical history form[4] included the following list of medical conditions: speech/cognitive delay, food allergies, gait issues, and "possible Autism Spectrum Disorder (ASD) (not diagnosed)." Ex. 16 at 57. A written summary[5] of A.S.'s medical history, also provided by the Sterlings, stated that, "[a]t his 2-year checkup, [A.S.]'s Pediatrician stated that [A.S.] may have Autism if other factors weren't ruled out." Ex. 14 at 7. This self-reported history also memorialized their view that A.S. "may have had a Vaccine Induced Autoimmune response, which was further continually aggravated by additional vaccines and his diet at the time, resulting in the progression of his ASD like symptoms." *Id.* at 8. The Sterlings expressed the concern that A.S. had experienced neurological inflammation or an encephalopathy. *Id.*

A.S. continued with physical, speech, and occupational therapy, and with visits to Dr. Layton. *See generally* Ex. 2; 14; 16. Under Dr. Layton's orders, A.S.'s hair was tested for the presence of elements such as aluminum, copper, lead, and nickel. Ex. 16 at 18–22. Aside from billing statements from Dr. Layton's office, no medical records (from Dr. Layton or other providers) support a diagnosis of encephalopathy for A.S.

II. Procedural History

After being filed in May 2016, the case was assigned to Chief Special Master Dorsey. Following a January 12, 2017 status conference, the Chief Special Master issued an order in which she noted her preliminary view that A.S. may have autism (a fact Petitioner had denied), emphasized that claims of vaccine-caused ASDs have consistently been unsuccessful in the Vaccine Program, and directed Petitioner to amend his petition so as to clearly identify A.S.'s diagnosis. Order at 1, filed Jan. 13, 2017 (ECF No. 17). Petitioner filed his Amended Petition on April 14, 2017, alleging injuries including neurologic neglect syndrome, expressive language disorder, unspecified disorders of the nervous system, and immune dysfunction. Am. Pet. at 3. Respondent filed his Rule 4(c) Report on June 2, 2017, arguing that A.S.'s medical records suggested a diagnosis of autism, and requesting the claim's dismissal. *See generally* Rule 4(c) Rep.

The Chief Special Master subsequently conducted a status conference with the parties, during which Petitioner conceded that A.S. had been diagnosed with autism. Order at 1, filed Aug. 17, 2017 (ECF No. 28). She also cautioned Petitioner that "without a specific vaccine-

[4] The medical history form does not bear a date.

[5] The written summary also does not bear a date.

related injury other than autism, this case lacks reasonable basis," and warned that "unless [P]etitioner can demonstrate from the medical records that A.S. suffered a vaccine-related injury other than autism," she would not reimburse attorney's fees or costs, including expert costs. *Id.* The following month, the Chief Special Master issued an order directing Petitioner to show cause why his case should not be dismissed. Order to Show Cause, filed Sept. 25, 2017 (ECF No. 30). The Order emphasized that "[P]etitioner and his counsel have been disingenuous with the court about A.S.'s autism diagnosis," as A.S. was diagnosed with regressive autism by Dr. Richard Layton in 2015. *Id.* at 3.

Petitioner responded to the Show Cause Order with a status report on October 24, 2017. ECF No. 31. Chief Special Master Dorsey thereafter issued an order addressing that status report, in which she noted that Petitioner had again failed to identify A.S.'s specific diagnosis. Order, filed Oct. 25, 2017 (ECF No. 33). While reiterating her prior warning that the case would lack a reasonable basis unless Petitioner failed to demonstrate that A.S. suffers from a specific vaccine-related injury other than autism, she nevertheless permitted the case to move forward. *Id.* at 2.

Petitioner subsequently filed reports from two experts on December 26, 2017: the first from James Lyons-Weiler, Ph.D., and the second from Toni Bark, M.D. Respondent also filed reports from two experts: one from Max Wiznitzer, M.D., and one from Jeffrey Johnson, Ph.D.

Following the filing of these expert reports, Chief Special Master Dorsey reassigned the case to me on October 23, 2018. Order Reassigning Case (ECF No. 53). I held a status conference with the parties on November 1, 2018, at which time I expressed similar concerns about the claim's viability based on my review of the record. I informed the parties of my intention to resolve this matter based on written filings. *See* Order, filed Nov. 1, 2018 (ECF No. 55).

The parties filed briefs in support of their respective positions in the spring of 2019. *See generally* Mem.; Opp.; Reply. Petitioner's Memorandum was accompanied by a supplemental report from Dr. Lyons-Weiler. This matter is now ripe for resolution.

III. Expert Reports

A. Petitioner's Experts

1. Dr. Toni Bark

Petitioner filed one expert report from Toni Bark, M.D. *See generally* Ex. 31, filed Dec. 26, 2017 (ECF No. 37-2) ("Bark Rep."). Dr. Bark's curriculum vitae ("CV") was not filed in this case, but her report states that she received her B.S. from the University of Illinois and her M.D. from Rush Medical College. *Id.* at 2. She completed a residency in pediatrics at the University of Illinois in 1991, then held a "directorship" in the pediatric emergency room of Michael Reese Hospital from December 1991 to May 1993. *Id.* She provided no subsequent details of her

employment records, simply stating that she has a private practice which includes vaccine injury patients. *Id.*

In her five-page report, Dr. Bark discusses A.S.'s medical history, highlighting the temporal proximity between the vaccinations at his one-year well-child visit and his subsequent viral illness and purported onset of developmental regression. Bark Rep. at 4. She accepts the "diagnosis" of encephalopathy offered by Dr. Layton (found only in billing statements), making no mention of a possible ASD diagnosis. *Id.*

Dr. Bark does not opine conclusively on the question of whether vaccines caused A.S.'s illness. Bark Rep. at 4. Instead, she recommends genetic testing in order "to ascertain if issues are genetic or epigenetically induced by vaccinations." *Id.* Her explanation of how one or more vaccines could have caused A.S.'s illness is both difficult to follow and relatively devoid of citations to supportive medical literature. She points to vaccine adjuvants—in particular, aluminum—as potentially harmful agents, particularly at the genetic level. *Id.* at 3. "The deleterious effects of aluminum on gene activity can be compartmentalized to active chromatin subfractions," she writes, explaining that excessive aluminum levels can impair the ability of RNA and DNA "to adequately read out genetic information." *Id.* She also discusses the possibility of excessive aluminum entering the brain, asserting that "injected aluminum is taken up by the macrophages and can be carried into the brain causing chronic activation of the microglial cells." *Id.* She states also that "excessive oxidative damage" is possible, and could be confirmed by lab tests that would show whether "aerobic respiration has been changed to anaerobic due to mitochondrial damage." *Id.* at 4. In support for her remarks, Dr. Bark references two pieces of medical literature, neither of which was filed in this case. *Id.* at 5. She does not explain how either article supports her stated positions. *See generally id.*

2. Dr. James Lyons-Weiler

James Lyons-Weiler, Ph.D., filed two reports on Petitioner's behalf. *See generally* Ex. 27, filed Dec. 26, 2017 (ECF No. 34-2) ("Lyons-Weiler First Rep."); Ex. 67, filed Mar. 29, 2019 (ECF No. 62-2) ("Lyons-Weiler Second Rep."). As reflected in his CV, Dr. Lyons-Weiler received his B.A. from the State University of New York-Oswego, followed by a Master's degree in Zoology from the Ohio State University and a Ph.D. in ecology, evolution, and conservation biology from the University of Nevada in Reno. Ex. 28 at 1, filed Dec. 26, 2017 (ECF No. 34-3) ("Lyons-Weiler CV"). In his second report, he notes that he "helped create the field of Bioinformatics." Lyons-Weiler Second Rep. at 1.

Dr. Lyons-Weiler asserts that A.S. does not have autism, but rather has a vaccine-induced encephalopathy, which led to a developmental coordination disorder ("DCD") featuring sensory motor deficits. Lyons-Weiler First Rep. at 1. He clarifies in his second report that the primary injury, the alleged encephalopathy, occurred after A.S.'s one-year vaccinations (which he received on January 9, 2013)—despite the fact that the Amended Petition points to the *May* 2013

vaccinations as causal. Lyons-Weiler Second Rep. at 2. A claim based on an encephalopathic reaction well before May 2013 would also be untimely under the Program's three-year limitations period. Section 16(a)(2). However, Dr. Lyons-Weiler also asserts that the subsequent vaccinations A.S. received significantly aggravated his condition—though he does not specify which vaccines the aggravation could be attributed to. *Id.*

In his two reports, Dr. Lyons-Weiler consistently reiterates that while he does not find tht A.S. had autism, his proffered theory of causation involves "the very same processes known to be involved in the development of autism." Lyons-Weiler First Rep. at 5; *see also* Lyons-Weiler Second Rep. at 3. This process, Dr. Lyons-Weiler explains, involves thimerosal and aluminum present in vaccines. Lyons-Weiler First Rep. at 1, 3, 9. He offers a variety of mechanisms by which these vaccine components could cause harm, either alone or in conjunction with other factors. For example, he asserts that thimerosal inhibits the endoplasmic reticulum aminopeptidase 1 protein, thereby inhibiting the adaptive immune system. *Id.* at 1–2. Thimerosal and/or aluminum could cause "cellular immunological response dysfunction," he states. *Id.* at 6. For this reason, he points to A.S.'s hair testing results, which purportedly showed "slightly increased" levels of aluminum, and concludes that these results "indicat[e] either high exposure or metabolic failure of clearance, either of which is key evidence toward a finding of causality." *Id.* at 3.

In addition, Dr. Lyons-Weiler asserts that when children are given acetaminophen after receiving the MMR vaccine (in order to avoid a vaccine-related fever), the acetaminophen causes depletion of glutathione. Lyons-Weiler First Rep. at 5, 7. This glutathione depletion causes excitotoxicity, which "mimic[s] concussive brain injury, leading to chronic microglial activation." *Id.* at 5. Based on A.S.'s family history, Dr. Lyons-Weiler asserts that A.S. is predisposed to autoimmunity, and he concludes that one or more of the mechanisms he outlined would cause an encephalopathy, leading to developmental coordination disorder. *Id.* at 9. And as clarified in his second report, he identifies A.S.'s one-year vaccines as the most likely injurious ones, and postulates that this condition was significantly aggravated by "subsequent vaccinations that were within the 3-year window." Lyons-Weiler Second Rep. at 2.

B. Respondent's Experts

1. *Dr. Max Wiznitzer*

Max Wiznitzer, M.D., provided one written report on Respondent's behalf. Ex. A, filed Sept. 14, 2018 (ECF No. 51-1) ("Wiznitzer Rep."). Dr. Wiznitzer graduated from the honors program in medical education at Northwestern University, where he received a B.S. in medicine in 1975, followed by his M.D. in 1977. Ex. B at 1, filed Sept. 14, 2018 (ECF No. 51-13) He completed a three-year internship and residency in pediatrics at Cincinnati Children's Hospital, followed by a one-year fellowship in child development and developmental disorders at the Cincinnati Center for Developmental Disorders. *Id.* He also completed a three-year child

neurology fellowship at the University of Pennsylvania and Children's Hospital of Philadelphia, followed by a two-year National Institute of Health fellowship in disorders of higher cortical function in children at the Albert Einstein College of Medicine in the Bronx, New York (which involved working with children with ASDs). *Id.* Dr. Wiznitzer currently works as a professor of neurology at Case Western Reserve University, and as a pediatric neurologist at the University Hospitals of Cleveland in Cleveland, Ohio. *Id.* at 2. Dr. Wiznitzer holds board certifications in pediatrics and neurology. *Id.* at 5.

Much of Dr. Wiznitzer's twenty-nine-page report is dedicated to reviewing A.S.'s medical history, as well as the statements offered by Petitioner's experts. He disputes several key points made by Dr. Lyons-Weiler. First, he disagrees with Dr. Lyons-Weiler's characterization of A.S.'s condition. Wiznitzer Rep. at 19–20. While Dr. Lyons-Weiler asserts that A.S. has a DCD, Dr. Wiznitzer finds this diagnosis to be incorrect, as DCDs involve only motor deficits, and do not encompass the social, language, and attention deficits that A.S. has. Wiznitzer Rep. at 19. And while Dr. Lyons-Weiler believes A.S. cannot have autism because he lacks an intellectual disability, Dr. Wiznitzer points out that intellectual disability is not, in fact, a diagnostic criterion for ASDs. *Id.* at 20. Dr. Wiznitzer also disputes the plausibility of the causation theories put forth by Petitioner's experts. *Id.* at 19–21, 24–25. He explains that the proffered theories are unsupported by the cited literature. *Id.* at 21–24. Regardless of whether A.S. has autism or another unspecified neurodevelopmental disorder, Dr. Wiznitzer concludes that his condition was neither caused nor aggravated by any vaccine. *Id.* at 25.

2. Dr. Jeffrey Johnson

Jeffrey Johnson, Ph.D., provided one written report in support of Respondent's position. *See generally* Ex. C, filed Sept. 14, 2018 (ECF No. 52-1) ("Johnson Rep."). He opined that the literature cited by Dr. Lyons-Weiler uniformly did not provide support for his conclusions. *See generally id.*

As outlined in his report, Dr. Johnson received his B.S. in biology and M.S. in pharmacology from the University of Minnesota-Duluth. Johnson Rep. at 1. He received his Ph.D. in molecular and environmental toxicology from the University of Wisconsin-Madison. *Id.* He has served as a professor of pharmaceutical sciences and pharmacology—first at the University of Kansas Medical Center, and subsequently at the University of Wisconsin—since 1995. *Id.* Dr. Johnson performs research in the fields of neuroprotection, neuropharmacology, and neurotoxicology. *Id.*

In his thirteen-page report, Dr. Johnson walks through each piece of scientific literature cited by Dr. Lyons-Weiler and explains why it does not provide meaningful support for his opinions. Johnson Rep. at 4–12. For example, while Dr. Lyons-Weiler states that the presence of thimerosal in vaccines causes harm by preventing proteins that protect against infectious agents from being "properly trimmed," which causes disruption of "everyday immunological signaling,"

The very paper Dr. Lyons-Weiler cites in support for this contention includes a statement from the authors indicating that "the low dose of thimerosal in vaccines would *preclude* any systemic event." *Id.* at 4–5 (discussing Lyons-Weiler First Rep. at 2; A. Stamogiannos, et al., *Screening Identifies Thimerosal as a Selective Inhibitor of Endoplasmic Reticulum Aminopeptidase*, 1 ACS Med. Chemistry Letters 681, filed as Ex. 44 (ECF No. 58-5) (emphasis added)). In total, Dr. Johnson discusses twenty-two items of literature, explaining why each one does *not* support Dr. Lyons-Weiler's conclusions. *Id.* at 4–12.

IV. Parties' Respective Arguments

A. Petitioner

In both his initial Memorandum and his Reply brief, Petitioner offers no legal argument in support of his position that he is entitled to a compensation award. *See generally* Mem.; Reply. Instead, both filings contain numerous paragraphs taken directly from Dr. Lyons-Weiler's first report. *See, e.g.*, Mem. at 7; Reply at 8 (repeating verbatim entire paragraph found on page 9 of Lyons-Weiler First Rep.).

After restating several of Dr. Lyons-Weiler's various arguments in support of vaccine causation, Petitioner argues that A.S. does not have a "classical ASD diagnosis," but that even if he does have an ASD, this should not preclude a finding of entitlement. Mem. at 8. He argues further that Respondent has offered no alternative cause to A.S.'s injuries other than that he has autism. *Id.* Finally, he asserts conclusorily that he has satisfied the causation-in-fact test established by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005). *Id.*

In his Reply, Petitioner argues that Respondent's opposition brief consists of nothing more than "inappropriate and unhelpful" ad hominem attacks on Petitioner's experts. Reply at 1. Petitioner also reiterates that, even if A.S. has an ASD, this should not automatically disqualify him from entitlement to compensation under Vaccine Program precedent. *Id.* at 1–2. Following the first three paragraphs, the Reply brief is identical to Petitioner's initial Memorandum. *See generally* Mem.; Reply.

B. Respondent

In his brief arguing against an award of compensation, Respondent preliminarily maintains that A.S. did not experience an encephalopathy, and that his injury should not be characterized as such. Opp. at 5–9. He argues that Petitioner's experts are not qualified to opine on A.S.'s correct diagnosis (or on the question of vaccine causation). *Id.* at 5–6. Similarly, Respondent points out that Dr. Layton is not a specialist in pediatric neurology or neurodevelopment, thus rendering his opinion less persuasive. *Id.* at 8. Moreover, even within Dr. Layton's records, the encephalopathy "diagnosis" appears only in billing statements, not in

actual records or notes from A.S.'s visits with Dr. Layton. *Id.* Respondent asserts that Petitioner likely seeks to rely on this billing notation (which is not itself a diagnosis) to circumvent comparison to the Omnibus Autism Proceeding ("OAP") cases, a technique which has been repeatedly attempted without success by Program claimants alleging claims of ASD-like developmental regression and delay. *Id.* at 9 (citing seven Vaccine Program cases involving ASD claims characterized as encephalopathy or other injury).

Turning to the question of causation-in-fact, Respondent argues that Petitioner has failed to satisfy all three *Althen* prongs. First, he asserts that the theory offered by Dr. Lyons-Weiler is "meandering" and "incoherent," but to the extent that it can be understood, it is not scientifically sound. Opp. at 10. Several central elements of the theory—including whether thimerosal and aluminum adjuvants can cause adverse neurological effects, and the role of mitochondrial dysfunction—have been rejected in many past Program decisions. *Id.* at 10–11. Moreover, as explained in great detail by Respondent's experts, the literature cited by Dr. Lyons-Weiler does not support his position. *Id.* at 11 (citing Wiznitzer Rep. at 21–24; Johnson Rep. at 4–11). For these reasons, Respondent argues that Petitioner has not satisfied the first *Althen* prong by providing a reliable scientific theory of causation. *Id.*

Despite the deficiencies in Petitioner's proffered theory of causation, Respondent argues that A.S.'s documented clinical course does not include evidence of the various processes that would be expected under such a theory. Opp. at 12–13. For example, testing performed on A.S. did not reveal elevated levels of metal in his body, contrary to the assertions of Petitioner's experts—thus greatly undermining the assertion that A.S. was experiencing some kind of toxic process. *Id.* Therefore, Respondent argues that Petitioner has failed to satisfy the second *Althen* prong. And finally, Respondent argues that A.S.'s neurologic problems did not begin within a medically-acceptable timeframe after vaccination. *Id.* at 15. Medical records preponderantly show that his problems began more than six months after the May 2013 vaccinations, which Petitioner has not demonstrated to be a reasonable time frame to attribute causation to any of the vaccinations at issue. *Id.* Thus, Petitioner cannot satisfy the third *Althen* prong.

ANALYSIS[6]

At the outset, the question of how best to characterize A.S.'s condition must be resolved. Petitioner and his experts have alleged different injuries (or aggravation thereof) at various points in this case's history. In his Amended Petition, Petitioner asserts that A.S. suffers vaccine-caused

[6] In most entitlement decisions, I would typically include a full recitation of the legal standards applicable to a Program claim under the Federal Circuit's *Althen* test. *See, e.g., R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519, at *28–32 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review denied*, 127 Fed. Cl. 136 (2016). Here, however, in the interests of brevity, and because the claim asserts autism as an injury (a subject that has been litigated over and over again in the Program), I do not do so.

neurologic neglect syndrome, expressive language disorder, unspecified disorders of the nervous system, and immune dysfunction. Am. Pet. at 3. Dr. Bark accepts the "diagnosis" of encephalopathy offered by Dr. Layton. Bark Rep. at 4. Dr. Lyons-Weiler, whose expert reports form the basis for both of Petitioner's briefs in support of compensation, asserts that A.S. experienced a vaccine-induced encephalopathy shortly following his (statute of limitations-barred) January 9, 2013 vaccinations, leading to a DCD featuring sensory motor deficits. Lyons-Weiler First Rep. at 1. Dr. Lyons-Weiler also states that subsequent vaccinations significantly aggravated this condition—although his proffered theory focuses more on the question of causation than aggravation. Lyons-Weiler Second Rep. at 2; *see generally* Lyons-Weiler First Rep. Respondent, by contrast, argues that A.S.'s condition is best characterized as an ASD or similar developmental delay or neurologic condition. Opp. at 9.

The assorted conditions alleged in the Amended Petition—neurologic neglect syndrome, expressive language disorder, nervous system dysfunction, and immune dysfunction—appear to have been cherry-picked from differential diagnoses considered throughout A.S.'s various appointments with medical professionals as they attempted to find an explanation for his condition. *See, e.g.*, Ex. 2 at 26 (Dr. Clayville initially assessing A.S.'s developmental delay as expressive language disorder or possible ASD); Ex. 11 at 28 (occupational therapist characterizing A.S.'s condition as neurologic neglect syndrome). Neither party's experts discuss these various conditions as discrete entities, each of which was caused or aggravated by a vaccine. Instead, both of Petitioner's experts describe A.S. as having some form of brain injury or neurologic problem that would account for his overall condition. Consistent with these assessments, I will consider A.S.'s condition as a whole, not as a constellation of discrete diagnoses.

In light of the fact that A.S. has not undergone a formal ASD evaluation, I cannot definitively resolve, based on the medical record, the question of whether his neurologic condition is best considered an ASD (although the evidence in favor of that conclusion is fairly strong nonetheless). At a minimum, however, the medical records and both parties' expert reports do preponderantly establish that A.S. suffers from some form of neurologic condition resulting in developmental delay. This leads to the primary question at issue: whether A.S. experienced an encephalopathy any time in the first half of 2013 (whether after the January or May vaccinations) that could have precipitated it. Having reviewed the record, I find that whether the claim is construed as a Table or non-Table claim, Petitioner has not preponderantly established evidence of any post-vaccination encephalopathy.[7]

[7] To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to a vaccine identified on the Table that the petitioner or injured party received, or (2) that he suffered an injury that was actually caused by a vaccine. *See* §§ 11(c)(1), 13(a)(1)(A). Petitioner has not pled his claim as arising from the Vaccine Table, but he does allege that A.S. experienced an encephalopathy. I include discussion of the Table definition of encephalopathy for purposes of analysis.

First, an examination of the record does not uncover any evidence that A.S. likely suffered an encephalopathy as defined by the Table after receipt of the DTaP vaccine (the only one A.S. received that could be the basis for such a claim).[8] *See* 42 C.F.R. § 100.3(a)(II)(B) (2018). To succeed, a petitioner would need to establish *both* that the injured party experienced an "acute" encephalopathy—typically evidenced by a decreased change in consciousness (as that term is defined in the Qualifications and Aids to Interpretation, 42 C.F.R. § 100.3(c)(2) (2018)) of sufficient severity to warrant hospitalization—and that the encephalopathy subsequently became "chronic" (that is, it lasted for at least six months). *Thompson v. Sec'y of Health & Human Servs.*, No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017). Here, however, there is no evidence that A.S. suffered an encephalopathy shortly after vaccination, nor at any time thereafter. The medical records filed in this case do not establish that A.S. experienced any kind of reaction within seventy-two hours of the May 7, 2013 vaccinations, or in a similar timeframe after the January vaccinations. At A.S.'s subsequent checkup with Dr. Clayville on July 26th, the Sterlings *still* reported no post-vaccination reaction or other sign of an encephalopathy. Ex. 2 at 38–43.

Second, Petitioner is unable on this record to establish a non-Table encephalopathy. Although a causation-in-fact claim alleging encephalopathy is not subject to the Table's stringent defined requirements, it still must be supported by preponderant proof, and must establish more than a neurologically-derived symptom. Specific symptoms that would suggest an individual had experienced an encephalopathy include crying, insomnia, fever, moodiness, and irritability. *Cook v. Sec'y of Health & Human Servs.*, No. 00-331V, 2005 WL 2659086, at *14 (Fed. Cl. Spec. Mstr. Sept. 21, 2005); *Noel v. Sec'y of Health & Human Servs.*, No. 99-538V, 2004 WL 3049764, at *17 (Fed. Cl. Spec. Mstr. Dec. 14, 2004). But in this case, the first evidence of A.S.'s developmental delay was not recorded until January 27, 2014, more than *eight months* after the May 7, 2013 vaccinations. *Id.* at 21–26. And these symptoms (which Dr. Clayville initially characterized as an expressive language delay and possible ASD) cannot persuasively be pointed to as proof of "encephalopathy"—they are at most *sequelae* of an alleged encephalopathy, and therefore it is circular reasoning to propose that they prove A.S. also experienced an encephalopathy in the first place. *See R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519, at *34 n.80 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review denied*, 127 Fed. Cl. 136 (2016).

The only records supporting a diagnosis of encephalopathy are found in Dr. Layton's billing statements, but these fleeting references are unsupported even by Dr. Layton's *own* records from his visits with A.S. *Compare* Ex. 16 at 54–55 (billing statement with check mark next to "encephalopathy") *with* Ex. 16 at 3–21 (Dr. Layton's notes from several visits with A.S., making no mention of encephalopathy). With such weak support for the injury alleged, Petitioner's claim

[8] Encephalopathy following the pneumococcal or Hib vaccine (the other two vaccines A.S. received on May 7, 2013) is not recognized as a Vaccine Table injury. *See generally* 42 C.F.R. § 100.3(a) (2018).

of post-vaccination encephalopathy—Table or non-Table—cannot succeed.

Petitioner's other non-Table claim, alleging causation-in-fact or significant aggravation of some other neurologic condition—whether DCD or an ASD—fares no better. In discussing his proffered theory of vaccine causation in this case, Dr. Lyons-Weiler straightforwardly admits that he relies on "the very same processes known to be involved in the development of autism." Lyons-Weiler First Rep. at 5. My reasoning in this case is therefore properly influenced by the many prior Vaccine Program cases involving allegations of vaccine-caused ASD-like disorders. The decisions from those cases overwhelmingly suggest that vaccines do not cause ASDs or conditions with comparable neurologic sequelae.

Several years ago, more than 5,400 cases were initially filed under short form petition in the OAP, where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs*., No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately, a total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit

unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

Nothing about this case distinguishes it from either the OAP determinations, or the numerous subsequent cases that attempted unsuccessfully to establish a causation theory that was purportedly different from what had been litigated in the OAP. *See, e.g.*, *Rogero v. Sec'y of Health & Human Servs.*, No. 11-770V, 2017 WL 4277580, at *4–5 (citing eighteen unsuccessful post-OAP autism claims that went to hearing and thirteen post-OAP autism claims that were rejected without a hearing), *mot. for review denied*, slip op. (Fed. Cl. Jan. 11, 2018), *aff'd*, 748 F. App'x 996 (Fed. Cir. 2018).

The rare cases in which a claimant succeeded in establishing a vaccine-caused encephalopathy that produced developmental regression or ASD-like symptoms were Table claims, and they underscore the importance of *immediate* evidence of acute encephalopathy precipitated by a close-in-time vaccination. *See Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600, at *10 (Fed. Cl. Spec. Mstr. Sept. 21, 2015) (child with ASD-type symptoms experienced a Table encephalopathy; noting that he convulsed and vomited during car ride home after receiving vaccinations (possibly evincing a brief seizure), then became listless, unresponsive, and "basically catatonic" by the following day); *Bast v. Sec'y of Health & Human Servs.*, No. 01-565V, 2012 WL 6858040, at *35–36 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (discussing case report about Hannah Poling, a successful Vaccine Program claimant who alleged a Table encephalopathy claim for her autism-type symptoms; noting that Hannah developed a high fever, inconsolable crying, irritability, and lethargy, and refusal to walk within forty-eight hours after vaccination), *appeal dismissed sub nom. M.S.B. ex rel. Bast v. Sec'y of Health & Human Servs.*, 579 F. App'x 1001 (Fed. Cir. 2014). Outside these narrow circumstances, the Court of Federal Claims has made it clear that petitioners cannot successfully recast a claim that a vaccine caused autism into an encephalopathy claim, based on the logic that the neurologic symptoms associated with an ASD reflect an underlying brain injury. *See, e.g.*, *Cunningham v. Sec'y of Health & Human Servs.*, No. 13–483V, 2017 WL 1174448, at *5 (Fed. Cl. Jan. 25, 2017).

Ultimately, Petitioner's causation theory is fundamentally at odds with the sound reasoning found in so many well-reasoned Vaccine Program decisions. The weaknesses of this theory are further underscored by several factors. As explained persuasively by Dr. Johnson, the literature cited by Dr. Lyons-Weiler does not support his stated positions. *See* Johnson Rep. at 4–12. The meandering, confusing nature of Dr. Lyons-Weiler's reports, as well as his apparent disregard for well-accepted scientific principles, further weakens the credibility of his assertions. *See, e.g.*, Lyons-Weiler Second Rep. at 2 (accusing studies on vaccines and autism of data manipulation and fraud). In addition, and more fundamentally, Dr. Lyons-Weiler appears to be wholly unqualified to opine on the question of vaccine causation. His academic training centered on zoology and

ecology, not medicine or immunology, and he does not appear to have performed research or published peer-reviewed work on any subject relevant to the present matter. *See generally* Lyons-Weiler CV.

Conclusion

As noted above, over two years ago the chief special master (to whom the case was previously assigned) expressed the preliminary view that Petitioner's claim likely lacked reasonable basis. Nothing I have seen presented in Petitioner's arguments or expert reports leads me to reach a contrary conclusion—and such a reasonable basis deficiency underscores the rationale for the claim's dismissal.

As other decisions have observed, reasonable basis (a concept applied most commonly when evaluating if an attorney's work on an unsuccessful case should be compensated) is a *lesser* standard than the preponderance standard governing Vaccine Act claims, and looks to see if any objective proof exists that would render the claim feasible, even if its chances of success are low. *See Braun v. Sec'y of Health & Human Servs.*, No. 17-1571V, 2019 WL 3228040, at *4 (Fed. Cl. 2019) (citing *Austin v. Sec'y of Health & Human Servs.*, No. 10-362V, 2013 WL 659574 (Fed. Cl. Spec. Mstr. Jan. 31, 2013)). Thus, a claim that is dismissed for failing to meet the preponderant standard may still be supported by sufficient objective proof for a fees award (and hence possess reasonable basis). A claim lacking in reasonable basis, however, has virtually no chance of meeting the preponderance test.

Here, there is an extensive body of law discussing claims involving ASDs or developmental symptoms alleged to have occurred due to vaccination—and that caselaw (which existed at the time of this case's initiation) overwhelmingly establishes that such claims are almost never meritorious. As a result, a claim like this one (where there is virtually no evidence of an encephalopathy—the one objective finding that has been the basis for success in exceedingly rare instances) was not just unlikely to succeed; rather, it lacked sufficient objective proof for its assertion at all. My experience and reasoned judgment in adjudicating vaccine claims involving ASDs and similar neurodevelopmental disorders strongly informs my conclusion not only that this claim could not succeed where countless others failed, but that it lacks the foundational objective support for its assertion in the first place. Because Petitioner has not—despite due opportunity—shown otherwise, I must DISMISS his claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk SHALL ENTER JUDGMENT in accordance with this decision.[9]

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master